REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Claims 23, 36, and 38-42 were pending. Applicants hereby cancel claim 36 without acquiescence to any rejection and without prejudice to prosecuting the cancelled subject matter in a related divisional, continuation, or continuation-in-part application. Claims 23 and 38-42 have been amended and new claims 49 and 50 have been added to point out with greater particularity and distinctly claim certain embodiments of Applicants' invention. No new matter has been added to the application by these amendments. Support for the new and amended claims may be found throughout the specification, for example, at page 30, lines 21-34; page 31, lines 16-27 and 29-32; page 61, line 29 through page 64. Upon entry of the amendments submitted herewith, claims 23, 38-42, 49, and 50 will be pending and under examination.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)

The Examiner rejected claims 23, 36, 37, 38, 40, and 42 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner asserts that the specification does not describe relevant, identifying structural and functional characteristics of species within the claimed genus to convey to a person skilled in the art that Applicants possessed the claimed genus at the time of filing the application.

Applicants traverse this rejection and submit that the instant claims satisfy the written description requirement under 35 U.S.C. § 112, first paragraph. The presently claimed embodiments relate, in pertinent part, to a pharmaceutical composition, which comprises (a) an isolated polypeptide that consists of an amino acid sequence at least 90% identical to the full-length amino acid sequence set forth in SEQ ID NO:2; (b) an isolated polypeptide that comprises an amino acid sequence at least 95% identical to the full-length amino acid sequence set forth in SEQ ID NO:2; or (c) an isolated polypeptide comprising an antigenic fragment that consists of at least 15 contiguous amino acids of SEQ ID NO:2. In certain specific embodiments, the antigenic fragment is coupled to a carrier protein. As recited in the present claims, the polypeptides, and antigenic fragments of at least 15 contiguous amino acids thereof, included in the claimed pharmaceutical compositions are capable of eliciting an antibody that specifically binds to a

polypeptide consisting of the amino acid sequence of SEQ ID NO:2, and are capable of inducing an immune response against *Streptococcus pyogenes*.

As previously made of record, written description is adequate when the specification describes the claimed embodiments in sufficient detail to convey *to a person skilled in the art* that the Applicants were in possession of the claimed embodiments at the time of filing, even if each and every species encompassed by the claims is not explicitly described in the specification. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("Although [the applicant] does not have to describe exactly the subject matter claimed, … the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."). As suggested by *Vas-Cath*, applying a rigid framework would not be appropriate when ascertaining whether a particular written description is sufficient.

The Federal Circuit Court of Appeals has articulated that with respect to the biological art, "[p]recedent illustrates that the determination of what is needed in a specification to support generic claims related to biological subject matter depends on a variety of factors, including existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter" (*Capon v. Eshhar,* 418 F.3d 1349, 1359 (Fed. Cir. 2005), citing *In re Wallach*, 378 F.3d 1330, 1333-34 (2004); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004); *Singh v. Brake*, 317 F.3d 1334, 1343 (Fed. Cir. 2003)); (*see also* M.P.E.P. § 2163.02)). Therefore, the fundamental factual inquiry in determining adequacy of the written description focuses on the understanding of *a person skilled in the art* and whether *a person skilled in the art* would understand that Applicants were in possession of the claimed embodiments.

A person skilled in the art would readily appreciate that the specification sufficiently describes the species encompassed by the claims, given the exemplary amino acid sequence, SEQ ID NO:2, of a full-length *S. pyogenes* polypeptide (referred to as SHB-GAS-102 in the application). The SHB-GAS-102 polypeptide is a conserved polypeptide expressed by different serotype strains of *S. pyogenes* (*see, e.g.,* page 48, line 19 through page 54, line 4 and Tables 2 and 3 (Example 1)). The claims recite that in certain embodiments, the SHB-GAS-102

polypeptide has a structure that consists of an amino acid sequence at least 90% identical to SEQ ID NO:2 or that comprises an amino acid sequence at least 95% identical to the amino acid sequence set forth as SEQ ID NO:2. Thus, the present application has described that the structure of the polypeptides of the claimed pharmaceutical compositions differs by only 5-10% from the amino acid sequence of SEQ ID NO:2 (*see, e.g.,* 24, lines 25-27). Substitutions, if any, are those that have a minimal influence on the secondary structure and hydropathic nature of the polypeptide such that the polypeptide retains immunogenicity (*see, e.g.,* page 23, lines 15-29; page 26, lines 28-31). By describing the full-length sequence and defining the percent identity of polypeptides included in the claimed pharmaceutical compositions, the specification describes in sufficient detail the structure of the polypeptides, conveying to a person skilled in the art that Applicants possessed the claimed embodiments at the time of filing. In addition, by providing the detailed chemical structure, that is, the amino acid sequence (*i.e.,* SEQ ID NO:2), the present application therefore discloses the structure of polypeptide fragments consisting of 15 or more amino acids of SEQ ID NO:2 (*see also, e.g.,* page 19, line 13 through page 20, line 13; page 29, lines 8-10; Figure 2).

The written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics … *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics" (*see Enzo Biochem., Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing the U.S. Patent and Trademark Office Guidelines, 66 Fed. Reg. at 1106) (emphasis added); *see also* M.P.E.P. § 2163(II)(A)(3)(a)). Therefore, the written description requirement may be met for a genus if the specification adequately correlates the structure and function of the members of the genus.

Also, as previously made of record, the specification describes certain functional features that correlate with the described and recited structural features of a SHB-GAS-102 polypeptide and antigenic fragments thereof. SHB-GAS-102 polypeptides and fragments thereof are antigenic, that is, capable of inducing an immune response to *S. pyogenes* in a host and eliciting antibodies that specifically bind to the full-length polypeptide of SEQ ID NO:2 (*see, e.g.,* page 16, lines 24-30; page 17, lines 29-21, page 18, lines 8-20; *see also, e.g.,* page 18, lines

22-33; page 26, lines 14-21). As described in working examples, the SHB-GAS-102 polypeptide exhibited the following functional activities: (1) induced an immune response that included eliciting polyclonal antibodies that bind specifically to the SHB-GAS-102 polypeptide; (2) induced an immune response in rabbits that included eliciting polyclonal antibodies used to protect a host (*i.e.,* passive immunity) from lethal challenge by *S. pyogenes*; and (3) induced an immune response that protected animals from infection in an art-accepted animal model (*i.e.,* active immunity) (*see* page 61, line 9 through page 62, line 25 (Example 8); page 63, line 1 through page 64 (Example 9)). An antigenic fragment of a SHB-GAS-102 polypeptide is a contiguous portion of the SHB-GAS-102 polypeptide that has the same or substantially the same immunogenic activity as the polypeptide of SEQ ID NO:2, which includes the capability of raising an immune response, including production of antibodies, that specifically recognizes the exemplary SHB-GAS-102 polypeptide disclosed therein (*see, e.g.,* page 26, lines 18-21).

As previously made of record, the "written description requirement serves a teaching function, a "*quid pro quo*" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." See *University of Rochester v. Searle*, 358 F.3d 916, 922 (Fed. Cir. 2004) (emphasis added), quoting *Enzo*, 323 F.3d at 970. By providing the exemplary amino acid sequence of the SHB-GAS-102 polypeptide, describing that this polypeptide is conserved and expressed by different strains of *S. pyogenes*, and demonstrating that the polypeptide induces an immune response against *S. pyogenes*, which includes a protective immune response, Applicants have provided sufficient, meaningful disclosure related to the claimed pharmaceutical compositions and are entitled to claims of sufficient scope that adequately protect Applicants' inventive efforts.

The present specification describes structural features and the correlative functional features of the polypeptides included in the claimed compositions in direct contrast to the patent at issue in *Rochester*, to which the Examiner refers (*see* Office Action at page 3, third full paragraph). In *Rochester*, because *no compounds* were disclosed in the patent, the court summarized that the patent "does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods…and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art" (*see id.* at 929). However, the present claims relate to pharmaceutical

compositions comprising a genus of highly structurally related polypeptides because the polypeptide consists of an amino acid sequence at least 90% identical to SEQ ID NO:2 or comprises an antigenic fragment consisting of at least 15 contiguous amino acids of SEQ ID NO:2.

With regard to genus claims, the patent laws and rules do not require that all members of the claimed genus be produced, that every member of the genus be produced within a reasonable amount of time, or that every member of the genus be operable. According to the *Capon* court, "[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." *Capon v. Eschhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). Therefore, from the perspective of one of skill in the art, the test is simply whether the properties of the genus are generally predicted by the properties of the disclosed species.

Adequate written description of claims reciting a genus of polypeptides does not require that the specific amino acid sequence of each protein itself must be provided. Such a description is not required under 35 U.S.C. § 112, first paragraph, because the written description requires neither examples nor an actual reduction to practice. *See Falko-Gunter Falkner v. Inglis,* 448 F.3d 1357, 1366 (Fed.Cir.2006) ("A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples covering the full scope of the claim language.") ("An actual reduction to practice is not required for written description.")). (See *Rochester* at 1360, quoting *In re Storrs*, 245 F.2d 474,478 (1957) ("...while it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, the certainty required of the disclosure is not greater than that which is reasonable, having due regard to the subject matter involved"). Guidance regarding what is reasonable has been provided by the Supreme Court: "The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented" (*Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822),

quoted by the court in *Rochester*, discussing that "the language of the present statute is not very different in its articulation of the written description requirement" (*see Rochester* at 924-925).

As discussed herein, Applicants have described the recited structural features of the polypeptides according to common terminology used in the art (*i.e.,* at least 90% or 95% identity to the full-length amino acid sequence of SEQ ID NO:2 or comprising an antigenic fragment consisting of at least 15 contiguous amino acids of SEQ ID NO:2), and have correlated those structural features with the recited functional characteristics (*i.e.,* capability to generate antibodies having binding specificity for a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 2, and to induce an immune response to *S. pyogenes*). Thus, in view of the state of the art, given the present description and the high skill level of a person skilled in the art, a skilled person could envision and readily predict that many species would be operable other than those disclosed.

By contrast to the present claims, the claims at issue in *The Regents of the University of California v. Eli Lilly and Company* (119 F.3d 1559 (Fed. Cir. 1997)), to which the Advisory Action (dated July 28, 2009) refers, did *not* recite *any* amino acid or nucleic acid sequence, structure, or formula. Moreover, the Federal Circuit Court of Appeals, confirming that in *Eli Lilly* the term, "human insulin cDNA," conveyed no relevant structural or physical characteristics, further stated that, "[i]t is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement" (*see Enzo Biochem* at 964; *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313, 1332 (Fed. Cir. 2003)).

A disclosure naming a single species can support claims to a genus if, as here, the disclosure conveys to a person skilled in the art the characteristics common to all species. *See In re Curtis*, 354 F.3d 1347, 1355 (Fed. Cir. 2004). A disclosure of a single species may not be sufficient under the written description requirement when the evidence indicates that a person skilled in the art could not predict the operability of any species other than the one disclosed. *See id.* at 1358. The description relied upon in *In re Curtis*, however, is distinguishable from the present application, in that the description in the Curtis application recited only the common functional properties of the claimed genus and did not provide *any* structural description of the genus. *See id.* at 1355. By direct contrast, as discussed above and herein, Applicants have

provided much more, describing structural characteristics that correlate with described functional characteristics.

Accordingly, the specification describes the claimed pharmaceutical compositions comprising the polypeptides as recited with sufficient, relevant, identifying characteristics to convey to a person skilled in the art that Applicants possessed the claimed embodiments at the time the application was filed. Applicants therefore submit that the instant claims satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, and respectfully request withdrawal of this rejection.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)

The Examiner rejected claims 23, 36, 38, 40, and 42 under 35 U.S.C. § 112, first paragraph, asserting that the present claims are not enabled by the teachings in the specification. The Examiner asserts that the prior art evidences the high degree of unpredictability and that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention (*see* Advisory Action at page 4).

Applicants respectfully traverse this rejection and submit that, contrary to the Examiner's assertions, in view of the guidance and direction provided in the specification, the advanced state of the art, and the high level of skill of a person practicing the art, the specification enables a person skilled in the art to make and use the claimed pharmaceutical compositions, as recited, readily and without undue experimentation. (*See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The presently claimed embodiments relate, in pertinent part, to pharmaceutical compositions comprising an isolated polypeptide that (a) consists of an amino acid sequence at least 90% identical to the full-length amino acid sequence set forth in SEQ ID NO:2; (b) comprises an amino acid sequence at least 95% identical to the full-length amino acid sequence set forth in SEQ ID NO:2; or (c) comprises an antigenic fragment that consists of at least 15 contiguous amino acids of SEQ ID NO:2. In certain specific embodiments, the antigenic fragment is coupled to a carrier protein. As recited in the present claims, the polypeptides, and antigenic fragments thereof, included in the claimed pharmaceutical compositions are capable of eliciting an antibody that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO:2, and are capable of inducing an immune response against *S. pyogenes*.

As previously made of record, given the teachings in the present application, the state of the art, and the level of skill of a person skilled in the art, the skilled person can, routinely and without undue experimentation, determine whether species within the SHB-GAS-102 polypeptide genus, as recited in the present claims, exhibit the capability to induce an immune response to *S. pyogenes*, and the capability to generate an antibody that specifically binds to a protein consisting of the amino acid sequence of SEQ ID NO:2. Consistent with the purpose of the enablement requirement, the present specification teaches a person skilled in the art how to *make* and *use* the claimed pharmaceutical compositions comprising the polypeptide species as recited.

For example and as previously made of record, the specification teaches an exemplary, detailed polynucleotide sequence and the deduced amino acid sequence of the SHB-GAS-102 polypeptide (*see, e.g.,* SEQ ID NO:1 and SEQ ID NO:2, respectively). The specification provides detailed guidance for cloning and expressing the claimed polypeptides (*see, e.g.,* page 35 through page 38, line 5; page 41, line 11 through page 43, line 29; page 48, line 19 through page 52, line 25). Furthermore, a person skilled in the art can, routinely and without undue experimentation, determine whether a SHB-GAS-102 polypeptide antigenic fragment of 15 contiguous amino acids of SEQ ID NO:2 exhibits the capability to induce production of antibodies that bind specifically to the full-length SHB-GAS-102 polypeptide by using any one or more immunoassays, screening methods, and animal models routinely practiced in the art. *See In re Wands,* 858 F.2d 731 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity of some experimentation such as routine screening.") Thus, by using the guidance provided in the specification, a person skilled in the art may routinely, and without undue experimentation, make and use the claimed pharmaceutical compositions.

Applicants strongly disagree with the conclusion by the Examiner that the state of the art demonstrates that a person skilled in the art cannot make and use the presently claimed pharmaceutical compositions without undue experimentation, particularly with respect to pharmaceutical compositions comprising a polypeptide that comprises an antigenic fragment as recited. Applicants respectfully submit that each document cited by the Examiner has not been considered in its totality and also does not support a *prima facie* case for lack of enablement. As previously made of record, Kokolus (U.S. Patent No. 5,807,978), cited by the Examiner, when

read in its entirety fails to support the Examiner's assertion that a polypeptide comprising an antigenic fragment of the SHB-GAS-102 polypeptide is not enabled by the specification. Kokolus contributed to the state of the art at the time the present application was filed by describing a *method that may be routinely performed for identifying immunogenic epitopes on the basis of the amino acid sequence of a polypeptide.* Thus, Kokolus and publications and software programs referred to in the Reply and Amendment submitted January 12, 2009 in response to the Office Action (dated July 11, 2008) for identifying antigenic epitopes may be useful for making, readily and without undue experimentation, SHB-GAS-102 polypeptide antigenic fragments that comprise at least one antigenic epitope.

Holmes et al. (*Exp. Opin. Invest. Drugs* 10:511-19 (2001)), cited in the Advisory Action (dated July 28, 2009), also fails to support the Examiner's assertions. Holmes et al. describe an experiment by Murphy et al., referred to therein, in which an 8-amino acid peptide (aa716-723) of the antigen was used *successfully* to generate an antibody called 4G5 that bound to the full length, *native protein.* Holmes et al. observed that antibodies that specifically bound to other peptides but that did not bind to full-length antigen were generated by immunization with peptides of only six amino acids in length and *commented that longer peptides (such as that bound by the 4G5 antibody) may induce antibodies that bind to full-length native antigen* (*see, e.g.,* Holmes et al., page 513). Moreover, peptide immunogens have been used very successfully as protective immunogens in the microbiology art, including against *S. pyogenes* (*see, e.g.,* by way of nonlimiting example, Pinchuk et al., "A CD8+ T Cell Heptaepitope Minigene Vaccine Induces Protective Immunity against *Chlamydia pneumoniae*," *J. Immunol.* 174:5729-39 (2005); McGuire et al., "Nasal Immunization with Homogenate and Peptide Antigens Induces Protective Immunity against *Trichinella spiralis*," *Infect. Immun.* 70:7149-52 (2002); U.S. Patent No. 6,419,932; U.S. Patent No. 6,063,386; U.S. Patent No. 6,716,433).

As previously made of record, polypeptides can tolerate many substitutions, deletions, and/or insertions, and whether species within the claimed genus are obtained as a result from spontaneous mutations occurring in a natural environment or from recombinantly introduced mutations, these polypeptide species will likely retain the claimed functionality. Species within the genus of SHB-GAS-102 polypeptides, which have the recited functional characteristics, can be characterized using immunoassays, screening methods, and animal models

described in the specification and routinely practiced by a person skilled in the art (*see, e.g.,* page 19, lines 1-11; page 44, lines 24-29; see methods described at page 52, line 26 through page 53, line 24 (Example 1); page 61, line 29 through page 64 (Example 8)). Accordingly, the methods and techniques, which are described in the application and/or available and well known to those skilled in the art, may be used to make and practice the claimed subject matter. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative … if it is merely routine").

Also as previously made of record, the Examiner's basis for rejecting the claims for lack of enablement (citing Li et al. and Lederman et al.) appears to rely, in great part, on the possibility that a single amino acid substitution in the presently claimed polypeptide *might* abrogate binding of a specific antibody to that polypeptide. The Examiner asserts that because a single amino acid *may* result in loss of function of a given polypeptide, a person skilled in the art cannot predict that an immune response will be induced by polypeptide species within the recited genus of polypeptides. However, as previously made of record, because a polypeptide can tolerate substitutions at many positions, identification of a polypeptide species that has retained activity is far more predictable than identifying a polypeptide species with a single amino acid change that abrogates activity.

Applicants are not required to identify inoperative species that are not encompassed by the claims and also are not required to test every embodiment of an invention encompassed by a claim. As previously made of record, an applicant need not describe a large number of examples, particularly when (as here) the level of skill in the art is high and the teachings of the specification are ample. *See In re Strahilevitz*, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982) (finding that although the invention encompassed a large variety of compounds, a large number of examples would not be required because examples are not required to satisfy section 112, first paragraph). Moreover, even though a large number of polypeptide species may be made, Applicants are not required to list all operable embodiments of the invention and to exclude inoperable ones, if any. *See Atlas Powder Co. v. E. I. Dupont de Nemours & Co.,* 750 F.2d 1569, 1576 (Fed. Cir. 1984). See also, *e.g., In re Angstadt,* 537 F.2d 498, 503 (CCPA 1976) (opining that if *Rainer*, as improperly relied on by the dissent, "stands for the proposition that the disclosure must provide guidance which will enable one skilled in the art to determine,

w*ith reasonable certainty before performing the reaction*, whether the claimed product will be obtained…then *all* 'experimentation' is 'undue,' since the term 'experimentation' implies that the success of the particular activity is *uncertain*") (emphasis added)). Furthermore, "depriving inventors of claims which adequately protect them and limiting them to claims which *practically invite appropriation of the invention* while avoiding infringement inevitably has the effect of suppressing disclosure." *Id.* at 504 (emphasis added).

Applicants have provided abundant guidance, including working examples, that teach a person skilled in the art how to make and use pharmaceutical compositions comprising the SHB-GAS-102 polypeptide species, readily and without undue experimentation. Given the skill level of a person skilled in the art, the state of the art, and the present disclosure, if the claimed subject matter is limited to only a single, disclosed sequence, a person skilled in the art can, readily and with trivial effort, *appropriate* pharmaceutical compositions comprising polypeptides that are outside the scope of the claim by using routine, commonly practiced techniques. Such limited scope is not commensurate with Applicants' contribution to the medical art, describing an immunogen that may be useful for treating and preventing *S. pyogenes* infections.

In view of the guidance provided in the specification, the knowledge and predictability in the art, the presence of multiple working examples, the high level of skill in the art, and the scope of the claims, Applicants submit that a person skilled in the art can practice the presently claimed subject matter readily without undue experimentation. Therefore, the instant claims satisfy the enablement requirement under 35 U.S.C. § 112, first paragraph, and Applicants respectfully request withdrawal of this rejection.

REJECTION UNDER 35 U.S.C. § 102

The Examiner rejected claims 23, 36, and 38-42, under 35 U.S.C. § 102(b), asserting that the claimed subject matter is anticipated by Telford et al. (International Patent Application Publication No. WO 2002/34771) (Telford). The Examiner asserts that Telford teaches a composition comprising a polypeptide represented by SEQ ID NO:6346 and that the polypeptide has an amino acid sequence that is 100% identical to SEQ ID NO:2. The Examiner also asserts that Telford describes more than 5,000 polypeptides and that "one skilled in the

microbiology and immunology art knows how to formulate the immunogenic composition comprising said polypeptide to induce an immune response" (*see* Action, page 5, last paragraph; Advisory Action, paragraph bridging pages 4 and 5).

Applicants respectfully traverse this rejection and submit that Telford fails to teach or suggest each feature of the present claims. Telford fails to teach or suggest a pharmaceutical composition comprising a polypeptide that consists of an amino acid sequence at least 90% identical to the amino acid sequence set forth in SEQ ID NO:2, or that comprises an amino acid sequence at least 95% identical to SEQ ID NO:2 or that is identical to SEQ ID NO:2. The cited art also fails to teach or suggest a pharmaceutical composition that comprises a polypeptide comprising an antigenic fragment consisting of at least 15 contiguous amino acids of SEQ ID NO:2. Telford also fails to teach or suggest that in certain embodiments, the antigenic fragment is coupled to a carrier protein. Telford also fails to teach or suggest that the polypeptide, as recited in the claims, that exhibits the recited functional properties.

As previously made of record and discussed herein, Telford provides more than 5,000 open reading frames that putatively encode polypeptides that are expressed by *S. pyogenes* (also referred to as group A streptococcus) or *S. agalactiae* (also referred to as group B streptococcus) and provides no more than a generalized statement with respect to how the various putatively encoded polypeptides disclosed therein may be used. Telford provides no working examples or any data that teach that any of the putative *S. pyogenes* polypeptides may be useful as an immunogen for preventing or treating a *S. pyogenes* infection, which is in direct contrast to the teachings of the present application.

Telford fails to anticipate the present claims because Telford provides a generic disclosure regarding compositions and describes a genus of polypeptides from which a person skilled in the art could *not* envisage the particular pharmaceutical composition comprising the polypeptide species as described and claimed in the present application. On the basis of the minimal disclosure in Telford, a person skilled in the art would be unable to determine whether a composition that comprises a polypeptide of SEQ ID NO:6346 among the 5,000 polypeptides listed therein, is operable as a pharmaceutical composition (*see also, e.g.,* M.P.E.P. § 2121.01 ("The disclosure in an assertedly anticipating reference must provide an enabling disclosure of

the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation.")).

Telford suggests that each and every one of the polypeptides disclosed therein may be a useful antigen for a vaccine or a diagnostic. Given the knowledge in the art that the majority of polypeptides of a bacteria species are not suitable candidates for inducing an immune response against the bacteria, a person skilled in the art would not reasonably expect that each and every polypeptide described in Telford would be useful as a diagnostic or vaccine candidate. Thus, a person skilled in the microbiology and immunology arts would immediately understand that this statement in Telford is speculative and provides no guidance with respect to a pharmaceutical composition because Telford fails to teach which polypeptides are capable of inducing an immune response against *S. pyogenes*. In the passages to which the Examiner refers (*see* Office Action, page 5), Telford merely provides generic disclosure describing methods for identifying bacterial polypeptides and possible, theoretical uses for bacterial polypeptides.

The disclosure in Telford is analogous to a description of a large genus of compounds from which a person skilled in the art must select portions of teachings within the reference to arrive at a specific composition. With respect to the instant claims, a person skilled in the art could *not* select, without undue experimentation, a particular species of polypeptide described in Telford to determine which can be included in a pharmaceutical composition, particularly when no preferred embodiments are described (*see* M.P.E.P. § 2131.02, citing *Ex part A*, 17 U.S.P.Q.2d 1716 (Bd. Pat. App. & Inter. 1990)).

Accordingly, given the lack of guidance in Telford, a person skilled in the art could not make and use a pharmaceutical composition using the disclosure in Telford without undue experimentation. Telford has merely speculated that each of the nucleic acids, polypeptides, and related antibodies disclosed therein may be included in compositions; however, Telford has not placed a person having ordinary skill in the art in possession of the claimed pharmaceutical composition comprising the isolated polypeptide as recited.

Applicants submit that a *prima facie* case of anticipation under 35 U.S.C. § 102 has not been established. Accordingly, Applicants respectfully request withdrawal of this rejection.

Applicants respectfully submit that all claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Mae Joanne Rosok/

Mae Joanne Rosok
Registration No. 48,903

Enclosure: Supplemental Information Disclosure Statement

MJR:am

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

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